

a) an active agent containing an effective amount of valsartan or a pharmaceutically acceptable salt thereof ; and,

b) at least one pharmaceutically acceptable [additives] additive [suitable for the preparation of solid oral dosage forms by compression methods]

wherein the active agent is present in an amount of more than 35% by weight based on the total weight of the compressed solid [oral] dosage form.

2. A compressed solid [oral] dosage form according to claim 1 wherein the active agent is present in an amount of more than 50% by weight.

3. (Twice Amended) A compressed solid [oral] dosage form according to claim 1 wherein the active agent is present in an amount ranging from 57 to 62 % by weight.

4. (Twice Amended) A compressed solid [oral] dosage form according to claim 1 wherein the active agent consists entirely of valsartan or a pharmaceutically acceptable salt thereof in a dosage of from between about 10 and 250 mg.

5. (Twice Amended) A compressed solid [oral] dosage form according to claim 1 wherein the dosage range is from 40 to 160 mg.

6. (Twice Amended) A compressed solid [oral] dosage form according to claim 1 wherein the dosage is 40 mg, 80 mg or 160 mg.

7. (Twice Amended) A compressed solid [oral] dosage form according to claim 1 wherein the active agent consists of an effective amount of valsartan or a pharmaceutically acceptable salt thereof and an effective amount of hydrochlorothiazide (HCTZ).

8. A compressed solid [oral] dosage form which comprises [as therapeutic agents] an effective amount of valsartan or a pharmaceutically acceptable salt thereof; an effective amount of HCTZ; and,
at least one pharmaceutically acceptable [additives] additive. [suitable for the preparation of solid oral dosage forms by compression methods.]

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cont
9. (Twice Amended) A compressed solid [oral] dosage form according to claim 8 comprising a unit dose of about 10 to 250 mg of valsartan or a pharmaceutically acceptable salt thereof and a unit dose of about 6 to 60 mg HCTZ.
10. (Twice Amended) A compressed solid [oral] dosage form according to claim 8 comprising a unit dose of about 50 to 100 mg of valsartan or a pharmaceutically acceptable salt thereof and a unit dose of about 10 to 30 mg of HCTZ.
11. (Twice Amended) A compressed solid [oral] dosage form according to claim 8 comprising a unit dose of about 80 to 160 mg of valsartan or a pharmaceutically acceptable salt thereof and a unit dose of about 12.5 mg or 25 mg of HCTZ.
12. (Twice Amended) A compressed solid [oral] dosage form according to claim 8 which comprises microcrystalline cellulose as a pharmaceutically acceptable additive.
13. (Twice Amended) A compressed solid [oral] dosage form according to claim 8 which comprises crosslinked polyvinylpyrrolidone (PVP) as a pharmaceutically acceptable additive.
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14. A compressed solid [oral] dosage form according to claim 12 wherein the microcrystalline cellulose is present in an amount of from 15 to 25% by weight.
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15. A compressed solid [oral] dosage form according to claim 13 wherein the crosslinked PVP is present in an amount of from 10 to 30% by weight.
16. (Twice Amended) A compressed solid [oral] dosage form according to claim 8 in the form of a tablet.
17. (Twice Amended) A compressed solid [oral] dosage form according to claim 8 in the form of a dragee.
18. (Twice Amended) A process of forming a compressed solid [oral] dosage form containing more than 35% by weight of valsartan or a pharmaceutically acceptable salt thereof [as

defined in claim 8] and at least one pharmaceutically acceptable additive wherein the process comprises the steps of: [comprising the steps of]

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- i) [grinding] blending the [active agent] valsartan and at least one pharmaceutically acceptable [additives] additive to form a mixture;
 - ii) subjecting the mixture [a mixture of the ground active agent and additives] to compression to form a coprimate;
 - iii) converting the coprimate into a granulate; and,
 - iv) compressing the granulate to form the compressed solid [oral] dosage form.

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19. A process according to claim 18 wherein the compression step ii) is carried out using roller compaction or slugging techniques.

20. (Twice Amended) A process according [accroding] to claim 18 wherein step iii) is carried out by screening or milling the coprimate.

21. A process according to claim 18 wherein the granulate is compressed without first being sized.

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22. (Twice Amended) A process according to claim 18 wherein the granulate is formed under a pressure of from about 25 to about 65 kN.

23. Coprimates obtained by roller compaction or slugging according to claim 19.

24. Granulate obtained according to the process according to claim 18.

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25. (Twice Amended) A compressed solid [oral] dosage form produced according to [a method] the process as defined in claim 18.

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26. A method of treating hypertension, congestive heart failure, angina, myocardial infarction, [atherosclerosis] arteriosclerosis, diabetic nephropathy, diabetic cardiac myopathy, renal insufficiency, peripheral vascular disease, stroke, left ventricular hypertrophy, cognitive dysfunction, headache, or chronic heart failure, wherein the method comprises administering a compressed solid [oral] dosage form as defined in claim 1 to a host in need of such treatment.

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Please add the following new claims:

- 27 ~~28~~. A compressed solid dosage form according to claim 1 in the form of a tablet.
- 28 ~~29~~. A compressed solid dosage form according to claim 1 in the form of a dragee.
- 29 ~~30~~. A process of forming a compressed solid dosage form containing more than 35 % by weight of valsartan or a pharmaceutically acceptable salt thereof, an effective amount of HCTZ and at least one pharmaceutically acceptable additive wherein the process comprises the steps of:
- i) blending the valsartan, HCTZ and at least one pharmaceutically acceptable additive to form a mixture;
 - ii) subjecting the mixture to compression to form a coprimate;
 - iii) converting the coprimate into a granulate; and,
 - iv) compressing the granulate to form the compressed solid dosage form.
- 30 ~~31~~. A process according to claim 29 wherein the compression step ii) is carried out using roller compaction or slugging techniques.
- 31 ~~32~~. A process according to claim 29 wherein step iii) is carried out by screening or milling the coprimate.
- 32 ~~33~~. A process according to claim 29 wherein the granulate is compressed without first being sized.
- 33 ~~34~~. A process according to claim 29 wherein the granulate is formed under a pressure of from about 25 to about 65 kN.
- 34 ~~35~~. Coprimates obtained by roller compaction or slugging according to claim 30.
- 35 ~~36~~. Granulate obtained according to the process according to claim 29.
- 36 ~~37~~. A compressed solid dosage form produced according to the process as defined in claim 34.

37 ~~39~~. A method of treating hypertension, congestive heart failure, angina, myocardial infarction, arteriosclerosis, diabetic nephropathy, diabetic cardiac myopathy, renal insufficiency, peripheral vascular disease, stroke, left ventricular hypertrophy, cognitive dysfunction, headache, or chronic heart failure, wherein the method comprises administering a compressed solid dosage form as defined in claim 8 to a host in need of such treatment.

38 ~~40~~. A compressed solid dosage form according to claim 1 wherein the dimension ratio of the dosage forms length:width:height is 2.5-5.0:0.9-2.0:1.0.

39 ~~41~~. A compressed solid dosage form according to claim 1 wherein the dosage form has a length of approximately 10 to 11 mm, a width of approximately 5.0-6.0 mm and a height of approximately 3.0-4.0 mm.

40 ~~42~~. A compressed solid dosage form according to claim 1 wherein the dosage form has a length of approximately 15.0-16.0 mm, a width of approximately 6.0-7.0 mm and a height of approximately 3.5 to 5.0 mm.

41 ~~43~~. A compressed solid dosage form according to claim 1 wherein the dosage form has a diameter of about 8 to 8.5 mm and a depth of about 3 to 3.5 mm.

42 ~~44~~. A compressed solid dosage form according to claim 1 wherein the dosage form has a diameter of about 16 mm and a depth of about 6 mm.

43 ~~45~~. A compressed solid dosage form according to claim 8 wherein the dimension ratio of the dosage forms length:width:height is 2.5-5.0:0.9-2.0:1.0.

44 ~~46~~. A compressed solid dosage form according to claim 8 wherein the dosage form has a length of approximately 10 to 11 mm, a width of approximately 5.0-6.0 mm and a height of approximately 3.0-4.0 mm.

45 ~~47~~. A compressed solid dosage form according to claim 8 wherein the dosage form has a length of approximately 15.0-16.0 mm, a width of approximately 6.0-7.0 mm and a height of approximately 3.5 to 5.0 mm.

~~46~~ 48. A compressed solid dosage form according to claim 8 wherein the dosage form has a diameter of about 8 to 8.5 mm and a depth of about 3 to 3.5 mm.

~~47~~ 49. A compressed solid dosage form according to claim 8 wherein the dosage form has a diameter of about 16 mm and a depth of about 6 mm.

~~48~~ 50. The process according to claim 18 wherein the blending step includes grinding.

~~49~~ 51. The process according to claim 31 wherein the blending step includes grinding.

~~50~~ 52. The process of claim 18 wherein the coprimate is formed by compression in the absence of water.

~~51~~ 53. The process of claim 31 wherein the coprimate is formed by compression in the absence of water.

~~52~~ 54. A method of treating according to claim 26 wherein the compressed solid dosage form is orally administered to the host.

~~53~~ 55. A method of treating according to claim 39 wherein the compressed solid dosage form is orally administered to the host.

REMARKS

Reconsideration of the application in view of the above amendments and the following remarks is requested.

Claims 1-25, 28-55 are now in this case. By this amendment, claims 1-18, 20, 22, 25 and 28 are amended and claims 29-55 are added. No new matter has been added by this amendment. Support for the above amendments may be found in the specification as detailed below: